

Page 15, third full paragraph, is amended as indicated below:

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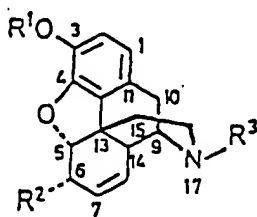
1 g (3.5 mMol) water-free morphine base were dissolved, while heating, in 100 ml methanol. Once the base had been completely dissolved in methanol, a solution of 756 mg (3.5 mMol) monomethylsebacic acid in 20 ml methanol was added. The combined solutions were concentrated in the rotary evaporizer. After ca. 48 h at 5 °C the morphine monomethyl sebacate had crystallized. Solvent residues were removed using a vacuum pump. The crystals had a melting point of 146 °C.

#### IN THE CLAIMS:

Amend claims 1-13 and 16 as follows and cancel claim 15. Appendix I is attached hereto having marked versions of said claims with amendments indicated by brackets and underlining.

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1. (Amended) Transdermal or transmucosal composition for administering at least one morphine alkaloid, the composition comprising at least one morphine alkaloid each as the acid addition salt thereof with an organic acid, each said morphine alkaloid being of the following Formula I:



(I)

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where  $R^1$  is selected from the group consisting of H,  $C_1$ - to  $C_6$ -alkyl residues;  $R^2$  is selected from the group consisting of the monad residues H, OH,  $OC(O)CH_3$ , whereby in this case the fourth valence of the (6)-C atom is occupied by H, or the dyad residues  $=O$ ,  $=CH_2$ ;  $R^3$  is selected from the group consisting of  $-CH_3$ , cyclopropyl, cyclobutyl and allyl;

the organic acid being selected from

monoesters of  $C_3$ - to  $C_{16}$ -dicarboxylic acids with monohydric  $C_1$ - to  $C_4$ -alcohols,

$C_2$ - to  $C_6$ - and  $C_8$ - to  $C_{16}$ -sulfonic acids,

substituted benzoic acids, selected from the group consisting of halogen, hydroxy, alkyl, hydroxyalkyl, alkoxyalkyl, alkoxy-substituted benzoic acids, aminosubstituted benzoic acids, aminosubstituted benzoic acids alkylated at the N atom,

substituted or unsubstituted 5-ring or 6-ring heterocycles comprising at least one N or S atom and having a carboxyl group function or branched or unbranched carboxypropyl or carboxybutyl groups as substituents,

saturated or unsaturated, substituted or unsubstituted, oxocarboxylic acids having 5 to 10 C atoms,

phenyl-substituted or phenoxy-substituted saturated C<sub>2</sub>- to C<sub>4</sub>-carboxylic acids,

aliphatic, aromatic or heterocyclic C<sub>2</sub>- to C<sub>12</sub>-amino acids, wherein one amino group is substituted with a substituted or unsubstituted C<sub>2</sub>- to C<sub>6</sub>-alkanoyl group or a substituted or unsubstituted benzoyl group,

the acid salt having a property of penetrating skin as defined by a flux of at least 2.34  $\mu\text{g}/\text{cm}^2\cdot\text{h}$ .

2. (Amended) Composition according to Claim 1, wherein the organic acid is selected from aliphatic monoaminomonocarboxylic acids, wherein the amino group is substituted with an unsubstituted C<sub>2</sub>- to C<sub>6</sub>-alkanoyl group or with a C<sub>2</sub>- to C<sub>6</sub>-alkanoyl group which is monosubstituted or polysubstituted with hydroxy,

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C<sub>1</sub>- to C<sub>4</sub>-alkoxy- or C<sub>1</sub>- to C<sub>4</sub>-hydroxyalkyl, or wherein the amino group is substituted with an unsubstituted benzoyl residue or with benzoyl residue which is mono- or polysubstituted with C<sub>1</sub>- to C<sub>4</sub>-alkyl, C<sub>1</sub>- to C<sub>4</sub>-alkoxy, C<sub>1</sub>- to C<sub>4</sub>-hydroxyalkyl, halogen, amino or hydroxy.

3. (Amended) Composition according to Claim 2, wherein the organic acid is selected from aliphatic C<sub>2</sub>- to C<sub>6</sub>-monoaminomonocarboxylic acids, wherein the amino group is substituted with an acetyl group or a benzoyl group.

4. (Amended) Composition according to Claim 1, wherein the organic acid is selected from:

hydroxy- (C<sub>1</sub>- to C<sub>4</sub>)-alkyl, C<sub>1</sub>- to C<sub>6</sub>-alkoxy-(C<sub>1</sub>- to C<sub>4</sub>)-alkyl-substituted or p- or m-hydroxy-substituted benzoic acids,

monoesters of C<sub>5</sub>- to C<sub>10</sub>-dicarboxylic acids,

C<sub>4</sub>- to C<sub>8</sub>-sulfonic acids.

5. (Amended) Composition according to Claim 1, wherein the acid is selected from C<sub>1</sub>- to C<sub>4</sub>-alkyl-substituted benzoic acids.

6. (Amended) Composition according to Claim 1, wherein the organic acid is hexanesulfonic acid, aminobenzoic acid or trimethylbenzoic acid.

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7. (Amended) Composition according to Claim 1, wherein the 5-ring or 6-ring heterocycle is a pyridine-carboxylic acid.

8. (Amended) Composition according to Claim 1, wherein the oxocarboxylic acid is a saturated or unsaturated 2-, 4-, 5- or 9-oxocarboxylic acid.

9. (Amended) Composition according to Claim 8, wherein the oxocarboxylic acid is 5-oxopyrrolidine-2-carboxylic acid, levulic acid or oxodec-2-ene acid.

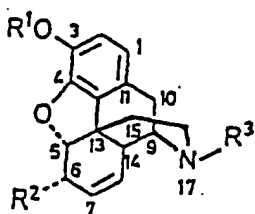
10. (Amended) Composition according to Claim 3, wherein the organic acid is acetylglycin or hippuric acid.

11. (Amended) Composition according to any one of Claims 1 to 10 and 17 to 25, wherein the morphine alkaloid is morphine, codeine, heroin, ethylmorphine, levorphanol or hydromorphone.

12. (Amended) Composition according to Claim 1, comprising a solution or suspension of the acid addition salt in glycerin, ethylene glycol, dimethyl isosorbide, oleic acid and/or dimethyl sulfoxide.

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13. (Amended) Acid addition salts of morphine alkaloid and organic acid, said morphine alkaloid having the following Formula I:



(I)

where  $R^1$  is selected from the group consisting of H,  $C_1$ - to  $C_6$ -alkyl residues;  $R^2$  is selected from the group consisting of the monad residues H, OH,  $OC(O)CH_3$ , whereby in this case the fourth valence of the (6)-C atom is occupied by H, or the dyad residues  $=O$ ,  $=CH_2$ ;  $R^3$  is selected from the group consisting of  $-CH_3$ , cyclopropyl, cyclobutyl and allyl;

the organic acid being selected from

monoesters of  $C_3$ - to  $C_{16}$ -dicarboxylic acids with monohydric  $C_1$ - to  $C_4$ -alcohols,

C<sub>2</sub>- to C<sub>6</sub>- and C<sub>8</sub>- to C<sub>16</sub>-sulfonic acids,

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halogen, p- and m-hydroxy, alkyl, hydroxyalkyl, alkoxyalkyl and/or alkoxy-substituted benzoic acids, aminosubstituted benzoic acids, aminosubstituted benzoic acids alkylated at the N atom,

substituted or unsubstituted 5-ring or 6-ring heterocycles comprising at least one N or S atom and having a carboxyl group function or branched or unbranched carboxypropyl or carboxybutyl groups as substituents,

saturated or unsaturated, substituted or unsubstituted, oxocarboxylic acids having 5 to 10 C atoms,

phenoxy-substituted saturated C<sub>2</sub>- to C<sub>4</sub>-carboxylic acids,

aliphatic, aromatic or heterocyclic C<sub>2</sub>- to C<sub>12</sub>-amino acids, wherein one amino group is substituted with a substituted or unsubstituted - C<sub>2</sub>- to C<sub>6</sub>-alkanoyl group or a substituted or unsubstituted benzoyl group

the acid salt having a property of penetrating skin as defined by a flux of at least 2.34  $\mu\text{g}/\text{cm}^2\cdot\text{h}$ .

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16. (Amended) A lotion, ointment, creme, gel, spray, iontophoretic device, transmucosal therapeutic system or transdermal therapeutic system, the transdermal therapeutic system including a backing layer which is permeable or - impermeable with respect to the active substance, and a reservoir layer, comprising a composition according to Claim 1.

Please add the following claims.

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-- 17. Composition according to Claim 1, wherein the alkyl residues are selected from methyl, ethyl, propyl, i-propyl and  $C(OH)CH_3$ .

18. Composition according to Claim 1, wherein the bond at  $C_7/C_8$  is saturated.

19. Composition according to Claim 1, wherein a nitroxyl group is present at  $N_{17}$ .

20. Composition according to Claim 1, wherein the alcohol of the monoester is methanol.



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21. Composition according to Claim 1, wherein the carbonyl group function of the 5-ring or 6-ring heterocycles is selected from carboxy, carboxymethyl and carboxyethyl.

22. Composition according to Claim 21, wherein the dicarboxylic acids of the monoesters are suberic acid, azelaic acid and sebacic acid.

23. Composition according to Claim 4, wherein the sulfonic acid is hexanesulfonic acid.

24. Composition according to Claim 5, wherein the acid is selected from C<sub>1</sub>- to C<sub>4</sub>-trialkyl-substituted benzoic acids.

25. Composition according to Claim 7, wherein the pyridine-carboxylic acid is nicotinic acid or lipoic acid.

26. Acid addition salts according to Claim 13, wherein the alkyl residues are selected from methyl, ethyl, propyl, i-propyl and C(OH)CH<sub>3</sub>.

27. Acid addition salts according to Claim 13, wherein the bond at C<sub>7</sub>/C<sub>8</sub> is saturated.